

REMARKS

Claims 1-33 and 37-41 are pending in this application. Claims 18 and 39-41 are canceled. Claims 1, 17 and 31 are amended herein. Support for the claim amendments is provided by the specification at, e.g., page 6, lines 4-8. Accordingly, no new matter is added by way of these amendments. Applicants respectfully request entry of the claim amendments and reconsideration in view of the following remarks. Claims 1-17, 19-33, 37 and 38 are now pending.

Substance of Interview

Applicants thank the Examiner for the courtesy of a telephonic interview between Examiner Fay and the undersigned on September 24, 2008 to discuss the imposition of finality in this case. The Applicants acknowledge and agree with the summary of the interview provided by the Examiner in the Office communication mailed on November 17, 2008.

Rejection Under 35 U.S.C. § 103

Claims 1-33 and 37-41 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over WO 98/34644 for reasons of record. [Applicants believe the Examiner meant to cite the Office Action of November 29, 2007, not November 21, 2008 as indicated.] Applicants traverse the rejections for reasons of record, as well as at least the following reasons.

Solely to advance prosecution, the claims are amended herein as indicated. As amended, claims 1 and 17 (and claims 2-16, 19-30, 33, and 37-38 which depend thereon) relate to a two-step method, comprising exposing a tissue area containing a photosensitizing agent to normal dose PDT treatment, followed immediately by exposing a tissue area that overlaps with or is adjacent to the treated tissue area to low dose PDT, where the area exposed to low dose PDT is concentric with but larger than the area exposed to the normal dose PDT treatment, and the exposure is for a time sufficient to reduce or treat inflammation arising from the normal dose PDT treatment.

As amended, claims 31 and 32 relate to a method of treating unwanted neovascularity of an eye, comprising providing a first dosage of irradiation to a treatment area to treat the unwanted

neovasculature, followed by a second, lower dosage of irradiation to a treatment area and an additional area adjacent to the treatment area to reduce the effects of inflammation arising from the first dosage of irradiation, wherein the area exposed to the lower dosage of irradiation is concentric with but larger than the area exposed to the first dosage of irradiation.

As previously noted by the Applicants, WO 98/34644 reports that a single low-dose PDT treatment may be used to reduce or prevent the effects of inflammation in an “injured tissue” or a “pre-injured tissue” in the absence of any other photodynamic therapy. *See, e.g.*, WO 98/34644 at page 17, lines 3-19. The Examiner asserts that the two-step treatment methods of the instant invention do not create a patentably distinct use, because it would be expected that low dose PDT treatment would be done after injury has occurred or is expected to happen.

The Examiner acknowledges that WO 98/34644 does not teach a method of reducing inflammation in tissues exposed to normal dose PDT treatment, or in tissues overlapping with tissues treated with normal dose PDT. Nevertheless, the Examiner asserts that in view of WO 98/34644, it would have been obvious to use low-dose PDT to treat inflammation caused by normal dose PDT, allegedly because normal dose PDT is known to cause inflammation. The Examiner rejects as unpersuasive the Applicant’s argument that one of skill in the art would not have had a reasonable expectation of success that treatment of tissues already inflamed by normal dose PDT with additional PDT, albeit at a lower light dose, would be beneficial to reduce inflammation. The Examiner has provided no motivation or other rationale based on the teachings of WO 98/34644 that would lead one of skill in the art to pursue such a counterintuitive course of treatment.

The Examiner further asserts that the use of low dose PDT treatment on tissues overlapping with or adjacent to tissues treated with normal dose PDT would also have been obvious, “considering that the tissues overlapping with the tissues subjected to photodynamic therapy are considered to be pre-injured tissues.” *See* Office action mailed November 29, 2007 at page 3. The Applicants respectfully disagree with the Examiner’s conclusory statement that overlapping tissues constitute “pre-injured” tissues as described by the reference, and respectfully note that the Examiner has pointed to nothing in WO 98/34644 that supports this assertion.

Assuming *arguendo* that a tissue area treated with normal dose PDT constitutes an “injured tissue” as described in WO 98/34644, the Applicants respectfully point out that the corresponding “pre-injured tissue” would be the tissue area to be treated with normal dose PDT prior to the normal dose PDT treatment. Thus, contrary to the Examiner’s assertion, the “pre-injured tissue” in the context of a tissue area that is “injured” (or expected to be injured) by normal dose PDT does not include tissue areas that are overlapping with but larger than or adjacent to the area treated with normal dose PDT.

The claims, as amended, include low dose PDT treatment of a tissue or treatment area concentric with but larger than the area treated with normal dose PDT. Accordingly, the claims relate to the use of low dose PDT to reduce or treat inflammation in a tissue area that comprises tissues adjacent to or overlapping with the area treated with normal dose PDT which are neither “injured” nor “pre-injured” as described in WO 98/34644. The Examiner has provided no basis for the suggestion that WO 98/34644 that would have led one of ordinary skill in the art to treat tissues which are neither “injured” nor “pre-injured” with low dose PDT, as claimed. Moreover, Applicants respectfully submit that one of skill in the art would not have had a reasonable expectation that doing so would lead to the reduction or prevention of inflammation, as claimed. In addition, nothing in WO 98/34644 teaches or otherwise suggests the selection of a tissue or treatment area for low dose PDT treatment that is both concentric with and larger than the area treated with normal dose PDT. Accordingly, Applicants respectfully submit that the selection of the area for low dose PDT treatment, as claimed, is nonobvious over the cited art.

In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **docket No. 273012011800**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 19, 2008

Respectfully submitted,

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